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CRO Industry Report

R&D, market challenges, investments, technology trends and regulatory frameworks for clinical trials today.

Photo Courtesy of PPD, part of Thermo Fisher Scientific

Growth in the global contract research organization (CRO) services market can be attributed to multiple factors including the need for novel clinical trial designs for complex cell and gene therapies and the advent of hybrid models with CRO-CDMO partnerships. These factors are expected to offer growth opportunities to players operating in this market.

Other key factors include the increasing investment in pharmaceutical R&D, the rising number of clinical trials, high cost of in-house drug development, which in turn is encouraging pharma and biopharma companies to opt for outsourcing.

The CRO services market was estimated to be worth $76.6 billion in 2023 and is projected to reach $127.3 billion by 2028, growing at a CAGR of 10.7% from 2023 to 2028 according to a report by MarketsandMarkets.[1]

In 2022, the data management services segment accounted for the highest growth rate. It is projected to grow at the highest CAGR owing to the factors such as the need to generate quality data for analysis and significance of data to meet the regulatory standards. Data management is gaining importance due to its role in the streamlined and uninterrupted development of drugs and medical devices.

Meanwhile, the growing need for novel clinical trial designs for complex cell and gene therapies is a key opportunity area for companies operating in this market. According to the report, the clinical research services subsegment accounted for the largest share of the type of segment in the CRO services market in 2022. The oncology segment accounted for the largest share of the global CRO services market in 2022, primarily attributed to the increasing number of drug discovery activities for oncology and the rising prevalence of cancer globally.

The MarketsandMarkets report notes that over the last decade, the drug discovery and development field has grown consistently. There has been a continuous growth in the number of clinical studies conducted, resulting in novel drug molecules entering various phases of the clinical drug development cycle.

Data from Pharma R&D Annual Review 2022 revealed that the number of drugs in the R&D pipeline grew from 17,737 in 2020 to 20,109 in 2022. According to the *ClinicalTrials.gov* website, the number of registered studies went up from 32,517 in 2019 to 36,770 in 2022 at a CAGR of 4.2% between 2019 and 2022.

Moreover, growth in the R&D pipeline of novel drugs is boosting the outsourcing of the drug development process with an aim to manage capacities and access scientific and process innovations to develop cost-effective and efficient drug molecules ultimately. This is expected to drive the CRO services market growth.

KEY R&D TRENDS

When it comes to pharma/biopharma R&D trends impacting outsourcing and services, technology and data are affecting human health and healthcare in ways never imagined, according to Jennifer West, senior director, business insights, Syneos Health.

"Data-driven insights enable teams to demonstrate how we're thinking strategically about executing a clinical study, planning HCP engagement or developing best practices for future outcomes," said West. For example, there has been increased preference for digital engagement strategies and increased expectations for data generation and data-driven insights from biopharmaceutical companies to accelerate patient recruitment.

"If we look at therapeutic areas, cell and gene therapy (CGT) continues to be a major focus for the industry, which brings a different level of complexity to clinical trials. Outsourcing for CGT and similarly, RNA therapies, requires specialized expertise, innovative approaches to patient recruitment and trial design, deep understanding of regulatory compliance and effective data management," said West.

Andrew MacGarvey, CEO of Phastar, said, "Big data is a key area of importance for the pharmaceutical industry, as well as biotechnology companies. The true value of data lies in its ability to unlock novel insights, facilitate well-informed decision-making, optimize processes, and 'dollar value' of data collected over the years." MacGarvey asserts that data science has emerged as a distinct discipline and swiftly established itself as an indispensable component.

"While technology continues to advance rapidly, the genuine value stems from the capacity to aggregate data and extract meaningful insights, such as harnessing cutting-edge machine learning methods and techniques, specialist expertise is key," said MacGarvey.

Another trend industry insiders are seeing is a shift to functional service provider (FSP) engagements and hybrid arrangements where FSP relationships augment full-service outsourcing (FSO) models and a desire for sponsors to have more "control" of their data. According to Lori Boyce, executive director, functional service partnership (FSP) solutions, PPD clinical research business, Thermo Fisher Scientific, there is an increased demand for data management FSP solutions where CRO partners work within client systems and processes so the sponsor has the ability to aggregate data across an asset, program or portfolio of work.

"A focus on 'sponsor of choice' and how best to partner with study sites to gain priority placement of their protocols in an environment that has seen a threefold increase in clinical trial volume over the past decade," said Boyce. "The role of the clinical research associate (CRA) continues to evolve, which has created new types of resources like 'site relationship leads' and 'site engagement leads,' both of which serve as a single point of contact between the site and the sponsor to support site relationships and reduce site burden."

Rhonda Henry, president, Emmes BioPharma, said that another significant trend is that sponsors are increasing their reliance on CROs for much more of the development pathway and regulatory submissions. "So, we do see a move toward full-service capabilities and global resources."

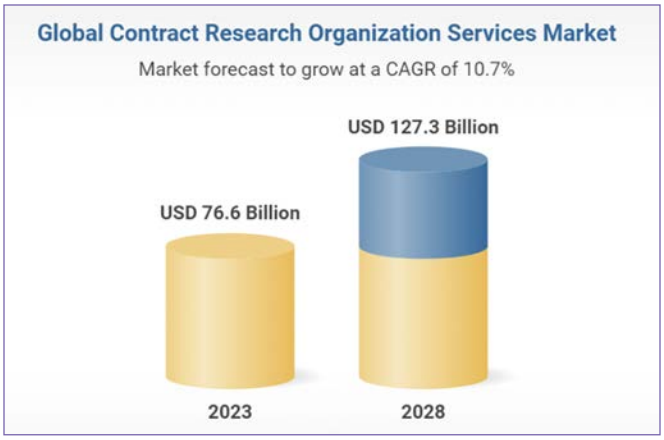

Figure 1. Global Contract Research Organization Services Market (Source: Research and Markets)

Henry added, "Consequentially, however, sponsors are increasingly competing for CRO resources, and access to a CRO with the right capabilities and expertise can be an issue. For example, there is a shortage of experienced clinical research professionals and this is negatively impacting the pharma/biopharma space, as well as sites. It is difficult for pharma/biopharma to hire staff with the needed expertise, which makes CROs so attractive."

MARKET CHALLENGES

While keeping a constant eye on the macroeconomic environment, Kort Schickfus, chief business officer, research and development solutions, IQVIA, said that sponsors still aim to enhance the flexibility needed for better trial engagement, especially to address challenges to inclusion of traditionally underserved populations in trials. "From telehealth to remote data collection to at-home nursing, lab, and imaging services, patient needs are more prominently addressed in trial design and operations," said Schickfus.

According to Schickfus, when striving to reduce patient burdens, sponsors and CROs must also address the potential for added site burdens that can come with technology integrations, changes in processes and resources and training needed to be effective in carrying out trial strategies as designed.

West of Syneos Health believes that the biopharmaceutical industry is currently facing several challenges, including margin deterioration; reimbursement and provider access hurdles; significant decline in funding, market valuations and mergers and acquisitions (M&A) activity; fewer blockbuster and high profitability drugs; continued pressure from generic brand exposure; and the consolidation of payers, healthcare systems, providers, and pharmacies.

"These challenges also make it more complicated to engage physicians and patients, making new product launches more difficult. At the same time, the industry is experiencing growing

demand for specialty drugs, pressure to improve R&D productivity, growing political and pricing pressures, and the transition of the healthcare industry worldwide from a volume-based to a value-based reimbursement structure," said West.

Industry experts assert that finding the right talent remains an ongoing challenge. "There is an industry shortage of skilled professionals, particularly in critical areas such as biometrics, statistics, and programming," said MacGarvey. "Historically, recruiting for these roles has proven difficult. Furthermore, the scarcity of data scientists exacerbates the situation, as their unique skill set is in high demand and relatively scarce."

MacGarvey pointed out that although the increased adoption of Python has expanded the pool of potential candidates, a deep understanding of the clinical trial environment is necessary, making it challenging to find suitable individuals. "Compounding this issue is the fierce competition for talent across various industries, as the demand for machine learning and AI expertise continues to soar. Recruitment, therefore, remains a persistent and formidable industry challenge," said MacGarvey.

With respect to what capabilities are needed for today's complex clinical trials, Lori Boyce at Thermo Fisher Scientific believes that flexibility is key to operationalizing in today's complex clinical trial environment. "Sponsors need to identify CRO partners who are adept at supporting them in a variety of outsourcing models. For example, when operationalizing studies on a global scale, each client may have different countries where their internal capabilities and needs fluctuate. If a sponsor has elected to run a study 'in house' and has geographies or countries included where they have insufficient staff or no staff, they may need a partner who can provide support for discrete tasks through functional service provider (FSP) engagements that provide specialized expertise," said Boyce.

Ching Tian, chief innovation officer, Emmes, said, "A CRO today cannot just rely on being operationally strong, they must be technologically strong as well – and this means having the tools to collect, capture, process, and analyze information. Over the next few years this will be a huge growth area and will also see CROs looking to link siloed solutions and data sets with new solutions. Emmes was one of the first in taking this technology-based approach and it's a real advantage having designed our own clinical data technology platform, built in house in partnership with clinical project teams.

In the current dynamic landscape, the adoption of an agile model has become indispensable, according to MacGarvey. "Increasingly, our customers and potential clients are approaching us with innovative demands, such as incorporating synthetic data into their upcoming trials. Given the rapid pace of technological advancements and its continuous acceleration, agility, and the capacity to swiftly respond are paramount for contract research organizations. Those CROs that fail to grasp and harness the potential of emerging technologies risk falling behind in this competitive industry."

INVESTMENT TRENDS

With respect to areas CROs are investing in, according to Matt Honan, vice president and head of corporate development at Emmes, CROs look to invest in areas that will help sponsors advance more quickly as the drug development pipeline evolves. "For example, we have seen lots CROs putting specialist divisions and teams together for orphan drug trials and cell and gene therapies. The other obvious trend and, one we have notably been a part of, is investing and acquiring other CROs—whether in new regions or for niche areas/capabilities—to achieve scale and have much more global capabilities," said Honan.

Kort Schickfus at IQVIA noted that through the COVID-19 pandemic, the need for patient-centered approaches to trial participation became very apparent. Digitized solutions, including safe and interactive telehealth platforms and connected devices that allow patients to be a part of important research that impacts themselves and others like them regardless of geographical location, can help improve trial access and engagement, especially for underserved communities.

"However, patient-centered solutions go beyond purposeful technology alone. For example, recent advancements in the self-collection of blood are allowing trial participants to now provide a blood specimen for lab testing from their home without visiting their trial site or having a home health professional visit," said Schickfus.

OUTSOURCING HOTSPOTS

According to Joel Morse, CEO and co-founder of Curavit Clinical Research, several factors influence today's outsourcing landscape, including available resources, regulatory changes, and advancements in technology. "With these factors in mind, we are seeing an increased reliance on outsourced expertise in virtual/remote clinical trial design and execution to keep costs down, along with experience in recruiting and enrolling a diverse trial participant population to meet new regulatory requirements and improve patient care for all."

"It's a big question and I think you could come at it from many different angles, but if we look at what we see at Emmes as the most promising growth areas then we continue to see good demand for vaccine and infectious diseases, ophthalmology and rare disease—all of which we are well known for," said Adam Mendizabal, vice president and director of Emmes' Cell and Gene Therapy Center. "But in the newer areas, then yes, cell and gene therapies continue to be area of considerable growth. What's most significant is that we now have advanced therapies in development for nearly every single therapeutic area—from oncology through to hematology, ophthalmology, cardiology, along with neurological targets and not to mention a major focus on rare diseases. From a CRO perspective this means we need a wide breadth of clinical indications experience to build the teams for each advanced therapy trial. This is also why you will see CROs building multi-functional Centers of

Excellence for cell and gene therapies so that you have these wide skill sets that can be tailored to the unique trial needs."

TECHNOLOGY TRENDS AND REGULATORY FRAMEWORKS FOR CLINICAL TRIALS TODAY

Finally, CRO executives contend that while new technology has provided big opportunities and empowered the shift toward digital and decentralized clinical trials, it also means there is a bigger gap in the capabilities and the needs of many trials. "Most of the small- to mid-sized sponsors don't have the in-house expertise or the bandwidth to go searching for innovative solutions and technologies on their own—and this has been a big trend in the last few years. CROs must bring not only that clinical and regulatory expertise in, but we are also coming forward as the main technology solution provider for sponsors," said Tian.

According to Panteli Theocharous, vice president, cell and gene therapy strategy lead, PPD Clinical Research Business, Thermo Fisher Scientific, some of the technology trends for clinical trials today include electronic clinical outcome assessment (eCOA), wearable devices and sensors, mobile apps, telemedicine, and artificial intelligence and machine learning (AI/ML) for data analysis, blockchain technology to improve the security and transparency of clinical trial data, and smart packaging to help enhance medication adherence.

Theocharous explains that while we haven't seen a huge shift in technology trends, as the industry continues its move toward an increased focus on patient centricity, it is seeing technology used in different ways. "For example, patient-facing technology, including patient apps and wearables, is being used to enhance the patient experience, which benefits recruitment and retention, as well as data collection and analysis by enhancing visibility for investigators and research teams," said Theocharous.

On the regulatory front, Morse said that the FDA's Draft Guidance in support of decentralized clinical trials, outlines the benefits of DCTs, such as enhancing convenience for trial participants, thus improving trial participant engagement, recruitment, enrollment, and retention of a meaningfully diverse clinical population. "This is a huge step toward improving equitable quality healthcare for all," he said. **CP**

References

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